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Russian Federation Sanitary/Phytosanitary/Food Safety Additions to Controlled Toxins in Food Products 2008

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Report Highlights:

In July 2008, Russia's Chief Medical Officer enlarged the list of controlled toxins in food products by dioxins, phytotoxins, ochratoxin A, and pentakhlorophenol, and established the Maximum Residual Limits (MRL) of these toxins in food products. The new requirements are stipulated in SanPin 2.3.2.2401-08 "Amendments and Changes #10 to the Sanitary and Epidemiological Regulations SanPin 2.3.2.1078-01 "Hygienic Requirements to Safety and Nutritional Value of Food Products". The new MRL of toxins in food products became effective on September 1, 2008.

Includes PSD Changes: No Includes Trade Matrix: No Trade Report Moscow [RS1] [RS]

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Summary

Russia's Chief State Sanitary Inspector¹ Gennadiy Onishchenko enlarged the list of controlled toxins in food products through approval of "SanPiN 2.3.2.2401-08 "Amendments and Changes #10 to the Sanitary and Epidemiological Regulations SanPin 2.3.2.1078-01 "Hygienic Requirements to Safety and Nutritional Value of Food Products". These amendments do not change existing tolerances, but rather establishes tolerances for products which previously where not included in the SanPiN. SanPiN 2.3.2.2401-08 consists of 6 (six) parts, or Attachments. Part 1 (Attachment 1) stipulates that the following controlled parameters and their Maximum Residual Limits (MRL) in food products² shall be added to hygienic and safety requirements for food products: "dioxins", "phytotoxins", "ochratoxin A", and "pentachlorophenol". Parts 2-6 (Attachments 2-6) determine changes and amendments to the hygienic and safety requirements for food for children. The SanPiN 2.3.2.2401-08 was introduced by the Chief Sanitary Inspector's Resolution #43 of July 16, 2008. The Resolution was registered at the Ministry of Justice of the Russian Federation on July 31, 2008. The new regulations, including MRL's requirements, came into force on September 1, 2008. In accordance with the Federal Law #52 of 1999 "On Sanitary and Epidemiological Wellbeing of the Population" compliance with the sanitary rules issued by the Chief Sanitary Doctor and registered at the Russian Ministry of Justice is mandatory³.

Below is an unofficial translation of the Resolution of the Chief Sanitary Inspector of the Russian Federation #43 of July 16, 2008 on approval of SanPiN 2.3.2.2401-08, and an unofficial translation of part 1 of the SanPiN 2.3.2.2401-08. Attachments 2-6 are not translated into English. The Russian text of the Resolution and texts of all attachments can be found on the website http://www.rospotrebnadzor.ru/docs/decision/?id=2113

¹ The status and authority of the Chief State Sanitary Inspector of the Russian Federation is similar to a Chief Medical Officer. The Chief State Sanitary Inspector of the Russian Federation is the Head of the Federal Service for Protection of Consumer Rights and Human Well-Being (Rospotrebnadzor).

² The framework SanPiN 2.3.2.1078-01 "Hygienic Requirements to Safety and Nutritional Value of Food Products" (registered at the Ministry of Justice of the Russian Federation on March 22, 2002, registration number 3326), and the attachments and additions to this SanPiN stipulate hygienic requirements for food products. The Russian text of the framework SanPin 2.3.2.1078-01 and text of some major additions and amendments to this framework SanPin can be found on the website: http://www.crc.ru/documents/fond/?ido=50. Rospotrebnadzor also develops hygienic requirements for agricultural products of plant origin, including MRL of pesticides. These hygienic norms for plants are stipulated in the document called Hygienic Norms of Content of Pesticides in Environment Objects HN 1.2.1323-03 (?? 1.2.1323-03), and in additions and amendments to these Hygienic Norms. In these norms the requirements and MRL are listed by chemical ingredients of pesticides, and MRL of the same pesticide may differ for different plants.

³ The Federal Law #52 of 1999 "On Sanitary and Epidemiological Wellbeing of the Population" stipulates that "It is compulsory for citizens, individual entrepreneurs, and legal entities to comply with the Sanitary Rules" (Article 39), and "Disciplinary, administrative, and criminal liability is admitted for breaching the sanitary legislation" (Article 55)

Resolution "On Approval of SanPiN 2.3.2.2401-08"

Begin text

RESOLUTION OF THE CHIEF STATE SANITARY INSPECTOR OF THE RUSSIAN FEDERATION DATED JULY 16, 2008, #43, MOSCOW "ON APPROVAL OF SANPIN 2.3.2.2401-08"

Registered at the Ministry of Justice of the RF on July 31, 2008, registration #12059

In accordance with the Federal Law dated 30.03.1999 # 52-FZ "On Sanitary and Epidemiological Wellbeing of the Population" (Collection of Laws of the Russian Federation, 1999, # 14, art. 1650; 2002 # 1 (p. 1), art. 1; 2003, # 2, art. 167; # 27 (p.1), art. 2700; 2004, # 35, art. 3607; 2005, # 19, art. 1752; 2006, # 1, art. 10; 2006, # 52 (p.1), art. 5498; 2007, # 1 (p.1), art. 21; 2007, # 1 (p.1), art. 29; 2007, # 27, art. 3213, 2007, # 46, art. 5554; 2007, # 49, art. 6070) and the Resolution of the Russian Federation Government dated 24.07.2000 # 554 "On Approval of the Statute of the State Sanitary and Epidemiological Service of the Russian Federation and the Statute of the State Sanitary and Epidemiological Regulations" (Collection of Laws of the Russian Federation, 2000, # 31, art. 3295, 2005, # 39, art. 3953).

I DECREE:

1. To approve SanPin 2.3.2.2354-08 "Amendments and Changes # 8 to the Sanitary and Epidemiological Regulations SanPin 2.3.2.1078-01 "Hygienic Reguirements to Safety and Nutritional Value of Food Products" (registered at the Ministry of Justice of Russia on 22.03.2002, registration number 3326), with changes and amendments introduced by the Resolution of the Chief State Sanitary Inspector of the Russian Federation dated 31.05.2002 # 18 "On Introduction of Changes into the Resolution of the Chief State Sanitary Inspector of the Russian Federation dated 14.11.2001 # 36" (registered at the Ministry of Justice of Russia on 04.06.2002, registration number 3499), by the Resolution of the Chief State Sanitary Inspector of the Russian Federation dated 15.04.2003 # 41 "On Putting into Force the Sanitary and Epidemiological Rules and Regulations SanPin 2.3.2.1280-03 – amendments and changes # 2 to SanPin 2.3.2.1078-01" (registered at the Ministry of Justice of Russia on 29.05.2003, registration number 4603), by the Resolution of the Chief State Sanitary Inspector of the Russian Federation dated June 25, 2007 # 42 "On Approval of SanPin 2.3.2.2227-07" - amendments and changes # 5 to SanPin 2.3.2.1078-01" (registered at the Ministry of Justice of Russia on 16.07.2007, registration number 9852), by the Resolution of the Chief State Sanitary Inspector of the Russian Federation dated 18.02.2008 # 13 "On Approval of SanPin 2.3.2.2340-08 "Amendments and changes # 6 to SanPin 2.3.2.1078-01 "Hygienic Requirements to Safety and Nutritional Value of Food Products" (registered at the Ministry of Justice of Russia on 11.03.2008, registration number 11311), by the Resolution of the Chief State Sanitary Inspector of the Russian Federation dated 05.03.2008 # 17 "On Approval of SanPin 2.3.2.2351-08 - amendments and changes # 7 to SanPin 2.3.2.1078-01" (registered at the Ministry of Justice of Russia on 03.04.2008, registration number 11465), by the Resolution of the Chief State Sanitary Inspector of the Russian Federation dated 21.04.2008 # 26 "On Approval of SanPin 2.3.2.2354-08 - amendments and changes # 8 to SanPin 2.3.2.1078-01" (registered at the Ministry of Justice of Russia on 03.04.2008, registration number 11741), by the Resolution of the Chief State Sanitary Inspector of the Russian Federation dated 23.05.2008 # 30 "On Approval of SanPin 2.3.2.2362-08 - amendments and changes # 9 to SanPin 2.3.2.1078-01" (registered at the Ministry of Justice of Russia on 06.06.2008, registration number 11805).

2. The above-mentioned sanitary regulations shall become effective on September 1, 2008.

G.G.Onishchenko

End text

Amendments and Changes #10 to SanPin 2.3.2.1078-01

Begin text

APPROVED By the Resolution of the Chief Sanitary Inspector of the Russian Federation dated July 16, 2008, #43

Amendments and Changes ? 10 To SanPiN 2.3.2.1078-01

HYGIENIC REQUIREMENTS TO SAFETY AND NUTRITIONAL VALUE OF FOOD PRODUCTS

Sanitary and Epidemiological Rules and Regulations SanPin 2.3.2.2401-08

The following amendments and changes shall be introduced into SanPin 2.3.2.1078-01.

1. In Attachment I «Hygienic Requirements to Safety and Nutritional Value of Food Products»:

1.1. Items 1.1.1. – 1.1.16., 1.2.1. - 1.2.4., 1.2.6., 1.2.8., 1.3.1. – 1.3.3., 1.3.6., 1.3.7., 1.4.1., 1.4.3., 1.4.4., 1.7.2. - 1.7.8., 1.9.6., 1.9.14., 1.10.2., 1.10.8., 1.10.9. shall be complemented with "dioxins", phytotoxins", "ochratoxin A", "pentachlorophenol" and their permissible limits in product groups with the following wording:

Index Product Group	Parameters	Permissible Limits, mg/kg, not exceeding	Note
1.1.1. Meat including semifinished products, newslaughtered, chilled, surface-	Dioxins * :	0,000003	Beef, mutton (fat basis)
frozen, frozen (all types of slaughter, commercial and wild animals)		0,000001	Pork (fat basis)
1.1.2. By-products of slaughter animals chilled, frozen (liver, kidneys, tongue, brains, heart), pork skin, food blood and its derived products	Dioxins*:	0,00006	Liver and products from liver (fat basis)
1.1.3. Beef, pork, mutton and other slaughter animal raw		0,000003	Beef, mutton (fat basis)
tallow (chilled, frozen), pork backfat and its derived products	Dioxins*:	0,000001	Pork (fat basis)

1.1.4. Sausage goods,		0.00000	From beef,
products from meat of all types	Dioxins*:	0,00003	mutton (fat basis)
of slaughter animals, ready- cooked meat foods		0,000001	From pork (fat basis)
1.1.5. Meat foods with by- products (pates, liverwurst, mock brawns, jellied meat and others), and blood. Cooked goods with by-products, blood, sausages, aspics (loaves, sausages, liverwurst, galantines)	Dioxins*:	see item 1.1.2	
1.1.6. Meat and cereal canned meat	Dioxins*:	see item1.1.1	
1.1.7. Canned by-products including pate (all types of slaughter and commercial animals)	Dioxins*:	see item 1.1.2	
1.1.8. Sublimated and heat dehydrated meat	Dioxins*:	see item 1.1.1	
1.1.9. Poultry meat including semi-finished products, chilled, surface-frozen, frozen (all types of poultry for slaughter, fowl)	Dioxins*:	0,000002	Poultry (fat basis)
1.1.10. By-products, semifinished products from poultry by-products	Dioxins*:	0,00006	Poultry liver (fat basis)
1.1.11. Sausage goods, smoked meat products, ready-cooked foods with poultry meat	Dioxins*:	see item 1.1.9	
1.1.12. Meat foods with poultry by-products, skins (pate, liverwurst and others)	Dioxins*:	see 1.1.10.	
1.1.13. Canned poultry (from poultry meat and meat and cereal including pate and mincemeat)	Dioxins*:	see item 1.1.9	
1.1.14. Sublimated and heat dehydrated poultry products	Dioxins*:	see item 1.1.9	
1.1.15. Eggs and liquid egg products (melange, white, yolk)	Dioxins*:	0,000003	Chicken eggs, and their derived products (fat basis)
1.1.16. Dry egg products (egg powder, white, yolk)	Dioxins*:	see item 1.1.15	
1.2.1. Milk, raw cream heat treated, buttermilk, milk whey, liquid fermented milk products including yogurt, sour cream, milk based drinks	Dioxins*:	0,000003	(fat basis)

1.2.2. Cottage cheese and curd products, paste-type milk protein products	Dioxins*:	see item 1.2.1	
1.2.3. Canned dairy products (milk, cream, buttermilk, whey, condensed milk products with sugar; condensed heat-treated milk)	Dioxins*:	see item 1.2.1	
1.2.4. Dry dairy products: cream, fermented milk products, drinks, ice-cream mixes, whey and buttermilk	Dioxins*:	see item 1.2.1	
1.2.6. Cheeses (hard, semi-hard, soft, pickled cheeses and cheese spreads)	Dioxins*:	see item 1.2.1	
1.2.8 . Butter	Dioxins*:	0,00003	
1.3.1. Live fish, fresh fish, chilled fish, frozen fish, minced fish, fillet, marine mammal meat	Dioxins*:	0,00004	
1.3.2. Canned fish and fish preserves	Dioxins*:	see item 1.3.1.	
1.3.3. Fish sundried, naturally dried, marinaded, fish culinary products and other fish foods ready for consumption	Dioxins*:	see item 1.3.1.	
1.3.6. Fish oil	Dioxins*:	0,000002	(fat basis)
1.3.7. Non-fish catch (shellfish, crustaceans, invertebrates, seaweed) and their derived products, amphibians, reptiles	Phycotoxins:		
	Shellfish paralyzant (saxitoxin)	0,8	Shellfish
- shellfish, crustaceans	Amnestic shellfish poison (domoic acid)	20	Shellfish
	Amnestic shellfish poison (domoic acid)	30	Crab innards
	Diarrhetic shellfish poison (ocadaic acid)	0,16	Shellfish
1.4.1. Food grain including wheat, rye, triticale, oats, barley, buckwheat, rice, corn, sorghum	Ochratoxin ?	0,005	Wheat, barley, rye, oats, rice
1.4.3. Cereal, oatmeal, flakes	Ochratoxin ?	0,005	Wheat, barley, rye, oat, rice
1.4.4. Wheat flour including flour for pasta, rye flour, triticale flour, barley flour, millet flour, rice flour, buckwheat flour, sorghum flour	Ochratoxin ?	0,005	Wheat, barley, rye, oat, rice
1.7.2. Vegetable oil (all types)	Dioxins*:	0,0000075	(fat basis)

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1.7.3. Products derived from processed vegetable oils and animal fats including fish oil (margarines,cooking butter, confectionery fats, mayonnaise, phosphatide concentrates)	Dioxins*:	see item 1.7.2 - vegetable oil based. see item 1.7.4. – animal fat based. see item 1.3.6. – fish oil based	(fat basis)
1.7.4. Beef, pork, mutton and other slaughter animal raw tallow (chilled, frozen, pork backfat chilled, frozen, salted, smoked)	Dioxins*:	0,000003 – beef fat 0,000001 – pork fat 0,000002 – poultry fat 0,000002 – animal fat compound	(fat basis)
1.7.5. Grease	Dioxins*:	see item 1.7.4	(fat basis)
1.7.6. Butter	Dioxins*:	0,00003	(fat basis)
1.7.7. Fatty products made of animal compounds including butterfat and vegetable fats	Dioxins*:	0,000002	Animal fat compound (fat basis)
1.7.8. Fish oil and marine mammal fat as a medicated product	Dioxins*:	see item 1.3.6	(fat basis)
1.9.6. Stabilizing thickeners, jelling agents (pectin, agar, carrageenan, and other gums)	Pentachlorophenol :	Not permitted (less than 0,001 mg/kg)	Guar gum, algaroba gum, adragant, karaya gum, tara gum, ghatti gum
1.9.14. Food concentrates	Dioxins*:	On the raw produ	
	DIOXIIIS .	(fat basis)	
1.10.2. Dietary supplements based mostly on lipids of animal and vegetable origin		see item 1.7.2, 1.7.3	Dietary supplement based on vegetable oils (fat basis)
		see item 1.7.8.	Dietary supplement based on fish oil (fat basis)
	Dioxins*:	see item 1.7.4.	Dietary supplement based on animal fats (fat basis)
		see items 1.7.3, 1.7.7.	Dietary supplement, fat compound based (fat basis)

1.10.8. Dietary supplements based on processed dairy and meat raw materials including by-products, poultry; arthropods, amphibians, apiarian products (royal jelly, propolis and others) – dry	Dioxins*:	see items 1.1.1, 1.1.2, 1.1.9, 1.1.10	Dietary supplement, raw meat based, including poultry by- products (fat basis)
		see item 1.2.1.	Dietary supplement, raw milk based (fat basis)
1.10.9. Dietary products based on fish, marine invertebrates, crustaceans, shellfish and other	Diovins*:	see item 1.3.1	Dietary supplement, fish based
seafood, plant marine bodies (seaweed and others) – dry	Dioxins*:	see item 1.3.6	Dietary supplement, fish oil based

Note:

- * the maximum level is irrelevant to products that contain less than 1% fat;
- hereinafter dioxins represent a sum of polychlorinated dibenzo-p-dioxins (PCDD) and polychlorinated dibenzofurans (PCDF) and are formulated as a sum of toxic equivalents (TE) in accordance with the WHO's 4 scale (WHO-TEFs):

TOXIC EQUIVALENTS (WHO-TEFs) **.

Congener	TE Value
Dibenzo-p-dioxins (PCDD)	
2,3,7,8-tetrachorodibenzodioxin	1
1,2,3,7,8-pentachlorodibenzodioxin	1
1,2,3,4,7,8–hexaclorodibenzodioxin	0,1
1,2,3,4,7,8-hexaclorodibenzodioxin	0,1
1,2,3,7,8,9- hexaclorodibenzodioxin	0,1
1,2,3,4,6,7,8- hexaclorodibenzodioxin	0,01
Octaclorodibenzodioxin	0,0001
Dibenzofurans (PCDF)	
2,3,7,8- tetrachorodibenzofuran	0,1
1,2,3,7,8-pentachorodibenzofuran	0,05
2,3,4,7,8-pentachorodibenzofuran	0,5
1,2,3,4,7,8-hexachorodibenzofuran	0,1
1,2,3,6,7,8- hexachorodibenzofuran	0,1
1,2,3,7,8,9- hexachorodibenzofuran	0,1
2,3,4,6,7,8- hexachorodibenzofuran	0,1
1,2,3,4,6,7,8-heptachorodibenzofuran	0,01
1,2,3,4,7,8,9- heptachorodibenzofuran	0,01
Octaclorodibenzofuran	0,0001

⁴ WHO is the abbreviation of the World Health Organization

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- ** 1 ng of TE means that this is a blend of PCDD and PCDF that corresponds to 1 ng 2.3.7.8-TCDD.
- 1.2. **In items 1.3.2. and 1.3.3.** the permissible level allowance shall be changed from 0,001 to 0,005 for the **"Benz(o)peren"** parameter in the "Permissible Limits, mg/kg, not exceeding" column.

Fnd text

List of Sections 2-6 of the SanPiN 2.3.2.2401-08

Sections 2-6 of the SanPiN 2.3.2.2401-08 amend Attachment 3 "Hygienic Requirements for Safety and Nutritional Value of Food for Children" of the SanPiN 2.3.2.1078-01 "Hugienic requirements to Safety and Nutritional Value of Food Products"

Section 2 amends Attachment 3 «3. Hygienic Requirements for Safety and Nutritional Value of Food for Children", Section "3.1. «Infant Food Products".

Section 3 amends Attachment 3 «3. Hygienic Requirements for Safety and Nutritional Value of Food for Children", Section «3.2. Food Products for Preschool and School Children"

Section 4 amends Attachment 3 «3. Hygienic Requirements for Safety and Nutritional Value of Food for Children", Section «3.3. Specialized Products for Children Clinical Nutrition"

Section 5 amends Attachment 3 «3. Hygienic Requirements for Safety and Nutritional Value of Food for Children", Section «3.5. Products for Pregnant and Nursing Women Nutrition»

Section 6 amends Attachment 3 «3. Hygienic Requirements for Safety and Nutritional Value of Food for Children", Section «3.6. Main Raw Materials and Ingredients Used for Manufacturing Children Food Products"

Relevant Reports

RS8055 FAIRS Country Report / Annual http://www.fas.usda.gov/qainfiles/200808/146295480.pdf

RS8050 Poultry and Products / Chlorine Use in Poultry Production Banned http://www.fas.usda.gov/gainfiles/200807/146295041.pdf

RS8049 Poultry and Products / Frozen Poultry for Further Processing to be Banned http://www.fas.usda.gov/gainfiles/200807/146295034.pdf

RS8045 Organic products / New SanPiN for Organic Products http://www.fas.usda.gov/gainfiles/200806/146294938.pdf